UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: BAYER CORP. COMBINATION ASPIRIN PRODUCTS MARKETING AND SALES PRACTICES LITIGATION	No. 1:09-md-2023-BMC
	AMENDED CLASS ACTION COMPLAINT
THIS DOCUMENT RELATES TO:	
	JURY TRIAL DEMANDED
Blank, et al. v. Bayer Healthcare LLC, Case No.: 1:09-cv-1548-BMC	

Plaintiffs, William Blank and Beverlysue Blank, husband and wife, on behalf of themselves and all others similarly situated, for their Amended Class Action Complaint against Defendant Bayer Healthcare LLC ("Bayer"), based upon personal knowledge as to their own actions and upon the investigation of counsel with respect to all other matters, complain as follows:

INTRODUCTION

1. Bayer sold and marketed directly to Plaintiffs and the Class, two over-the-counter ("OTC") pharmaceutical products which were not approved by the Food and Drug Administration ("FDA") and never should have been sold to *any* consumer. Bayer marketed these two products, "BAYER WOMEN'S Low Dose Aspirin + CALCIUM" ("Bayer Calcium") and "BAYER ASPIRIN With HEART ADVANTAGE" ("Bayer Heart Advantage") (collectively the "Combination Aspirins"), as combination OTC drugs and dietary supplements without the required regulatory approval. Thus, the safety and effectiveness of these drugs has not been reviewed, nor approved, by the FDA.

2. Bayer markets Bayer Heart Advantage with the claim that the drug "lowers cholesterol," and Bayer Calcium with the claim that the drug "fights osteoporosis." However,

treatments for heart disease and osteoporosis, such as Bayer's Combination Aspirins, must be reviewed by government scientists and cannot be sold over the counter in this manner.

3. Doctors traditionally prescribe aspirin to treat aches and pains and as a blood thinner for patients with heart disease. The FDA allows traditional pain relievers to be sold over-the-counter without review, as long as they include standard directions and labeling for consumers. But Bayer's Combination Aspirins lack proper directions for use, and illegally claim that the added ingredients in each medicine help fight specific diseases long-term.

4. However, taking aspirin long-term should be under a doctor's supervision, as the medicine is meant for short-term use. The long-term use of aspirin can cause serious side effects like gastrointestinal bleeding.

5. By placing the Combination Aspirins into retail stores, Bayer mislead and deceived Plaintiffs and the Class into believing that the products could be legally sold, had been approved by the FDA, and had been proven to be safe and effective for their marketed purposes when none of these things were true.

6. Bayer has been marketing Bayer Heart Advantage since early 2008 and Bayer Calcium since 2002. In fact, the Combination Aspirins should never have been sold, and Plaintiffs and the Class members have been damaged and are entitled to a refund.

JURISDICTION AND VENUE

7. This Court has personal jurisdiction over this lawsuit because Bayer's principal place of business is in this district, and therefore has sufficient contacts with this state and judicial district to permit the exercise of jurisdiction in compliance with traditional notions of fair play and substantial justice.

8. This Court has subject-matter jurisdiction over this nationwide class action pursuant to 28 U.S.C. § 1332 as amended by the Class Action Fairness Act of 2005 because the

matter in controversy exceeds $5,000,000, exclusive of interest and costs, and is a class action in which some Class members are citizens of states different than Defendant. *See* 28 U.S.C. § 1332(d)(2)(A).

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1391(b)(2) because Defendant resides in and conducts business in this judicial district, and because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in and near this judicial district.

PARTIES

10. Plaintiff William Blank is a citizen and resident of the State of New Jersey. Mr. Blank purchased and ingested Bayer Heart Advantage in New Jersey during the relevant period, and suffered ascertainable losses as a result of Defendant's actions as alleged herein.

11. Plaintiff BeverlySue Blank is a citizen and resident of the State of New Jersey. Ms. Blank purchased and ingested Bayer Calcium and Bayer Heart Advantage in New Jersey during the relevant period, and suffered ascertainable losses as a result of Defendant's actions as alleged herein.

12. Defendant Bayer HealthCare, LLC, is a Delaware corporation with a principal place of business in Morristown, New Jersey. Bayer HealthCare, LLC markets and sells both products which are the subject of this Complaint, and was the recipient of two warning letters from the FDA dated October 27, 2008 pertaining to the Combination Aspirins. Since the late 1800s, Bayer has been associated with aspirin. Plaintiffs and the Class members were led to believe that both products were part of the family of aspirin products for which Bayer had received regulatory approval to sell for their marketed purposes.

RELEVANT FACTS

A. FDA Procedures For The Approval Of New Drugs

13. Drug companies must apply to the FDA for approval to sell a new drug.

14. Since the Combination Aspirins constitute a "drug or drugs" pursuant to the Federal Food, Drug and Cosmetic Act, the FDA must be convinced of the safety and efficacy of these products before they could be marketed to humans. 21 U.S.C. § 321(g).

15. While some dietary supplements do not require FDA approval, the fact that both of these products included aspirin, with its intended use as an analgesic, rendered both products a drug, thereby triggering the FDA's requirements set forth above.

16. Despite this requirement, Bayer has promoted, advertised and marketed the Combination Aspirins without seeking or receiving FDA approval for either of them.

17. Even though Bayer marketed the drugs for OTC use, the representations made by Bayer on Bayer Heart Advantage concerning a reduced risk of cardiovascular disease, and on Bayer Calcium concerning a reduced risk of osteoporosis, were deceptive and misleading because any products touting their effects from a medical standpoint require physician supervision.

18. The warnings included with both products were likewise inadequate, and failed to advise consumers of the risks associated with ingesting these unapproved products.

19. Bayer knew that the Combination Aspirins were required to receive FDA approval but purposefully failed to do so before selling the drugs to Plaintiffs and the Class. In fact, the FDA has in the past specifically recommended that companies refrain from marketing products that combine both OTC drug and dietary supplement ingredients (except for products marketed under an approved new drug application).

20. For example, in May 2000, then Associate Commissioner for Policy, Margaret Dotzel, advised companies considering marketing products that combine or co-package dietary supplements and OTC drug ingredients that:

> These types of combination products raise a number of significant public health and policy issues. For example, the addition of a new ingredient to a legally marketed drug product could affect the safety and efficacy of the drug component. In addition, consumers may be confused about the degree of scrutiny FDA gives such combination products. Consumers may believe that both components have been subjected to the more stringent drug regulatory requirements when, in fact, only the drug component may have been reviewed by the agency for safety and effectiveness. Moreover, it is uncertain under what circumstances the disclaimer required by the Dietary Supplement Health and Education Act (DSHEA) (codified in 21 U.S.C. 403(r)(6)(C)) could appear on a combination product without furthering consumer confusion.[1]

21. Despite the fact that the FDA specifically recognized that the sale of products like the Combination Aspirins without FDA approval would serve to "confuse" consumers, Bayer marketed and sold the Combination Aspirins anyway. As further detailed below, Bayer thus deceived and confused Plaintiffs and the Class, and should provide a refund for their purchases.

B. Bayer Deceived Consumers By Marketing Bayer Calcium For The Treatment Of Osteoporosis And Cardiovascular Disease Despite Knowing That The FDA Had Not Approved It For Sale

1. Bayer knew that women are concerned about preventing and fighting osteoporosis, the most common bone disease among Americans, and actively preyed on those fears

22. In 2004, the U.S. Surgeon General warned that by 2020, half of all Americans older than 50 would be at risk for fractures from osteoporosis and low bone mass if no immediate action was taken by individuals at risk, doctors, health systems, and policymakers.

[1] *See* http://www.ahpa.org/portals/0/pdfs/08_0529_AHPA_to_FDA_OTC_DS_Combination_Products.pdf.

23. Osteoporosis, or thinning bones, is a serious condition that can result in tremendous pain with fractures. The most common bone disease some of the risk factors for osteoporosis include aging, being female, and low sex hormones such as during menopause.

24. The former Surgeon General reported that 10 million Americans over the age of 50 had osteoporosis, while another 34 million were at risk for developing osteoporosis. And each year, roughly 1.5 million people suffer a bone fracture related to osteoporosis.

25. Because there are no symptoms of this bone disease until an individual fractures a bone, suffers severe back pain or loses height, women are extremely concerned about the prevention and treatment of osteoporosis. Treatment and prevention includes calcium and vitamin D, regular exercise, and osteoporosis medications under a physician's care, if needed.

26. Once a physician deems a woman at risk or diagnoses her with osteoporosis, there are a number of *prescription* osteoporosis drugs called bisphosphonates that are approved for the prevention and treatment of osteoporosis. Biphosphonates help slow or stop the process of bone breakdown during remodeling. Other types of approved *prescription* medications for the treatment of osteoporosis include: Selective Estrogen Receptor Modulators, Calcitonin, Forteo (teriparatide), and hormone therapy.

27. The myth has been perpetuated throughout society that osteoporosis is a "grandmother's disease." However, the Surgeon General warned that one of the most dangerous myths about osteoporosis is that only women need to worry about bone health. In fact, the Surgeon General reported that the number of people who have osteoporosis is much greater than the number who report having the disease – four times as many men and nearly three times as many women; and that osteoporosis affects men and women of all races, and while bone weakness is more common in older Americans, building strong bones begins in childhood.

28. Bayer knows that women are concerned about preventing and fighting osteoporosis and plays on those fears. Notwithstanding the fact that men are just as at risk as woman and despite the fact that it did not receive regulatory approval to sell Bayer Calcium, Bayer preyed on women's fears by selling the Bayer Calcium that was not approved for sale.

29. According to the package labeling on Bayer Calcium, each caplet (tablet) contains, among other ingredients, 81 mg of aspirin and an undisclosed amount of calcium carbonate that includes 300 mg of elemental calcium. The product is prominently labeled as a "PAIN RELIEVER/CALCIUM SUPPLEMENT" and for "ASPIRIN REGIMEN" use.

30. Regarding the daily use of Bayer Calcium as a source of dietary calcium, the package labeling prominently features the statement: "Provides 300mg of Calcium Which Helps Strengthen Bones To Help Fight Osteoporosis." The package labeling also bears a health claim about calcium and reduced risk of osteoporosis (*see* 21 C.F.R. § 101.72), stating:

> Menopausal women and women with a family history of the disease are groups at risk for developing osteoporosis. Adequate calcium intake throughout life, along with a healthy diet and regular exercise, builds and maintains good bone health and may reduce the risk of osteoporosis. While adequate calcium intake is important, daily intakes above 2,000 mg may not provide additional benefits.

31. The package labeling also prominently features a glass of milk pictured in close proximity to these statements and to the name, "Bayer Women's Low Dose Aspirin + CALCIUM." This further represents that, like milk, Bayer Calcium is a source of dietary calcium.

32. Thus, Bayer intended to and did deceive consumers into believing that Bayer Calcium was approved by the FDA as safe and effective to mitigate, treat, or prevent osteoporosis.

2. Bayer also makes unapproved claims regarding the effectiveness of Bayer Calcium for long-term daily use in the prevention and treatment of cardiovascular diseases

33. Regarding the use of Bayer Calcium as a source of aspirin, the package labeling states that the analgesic is intended to treat pain. However, other statements and representations on the package suggest that the product is also offered for long-term daily use in preventing or treating cardiovascular diseases. For example, the product states: "Aspirin Protects Your Heart by Keeping Your Blood Flowing Freely," along with the statements "For more information on how to fight heart disease and stroke, visit the American Heart Association website at www.americanheart.org" and "Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen."

34. In addition, statements on the labeling enclosed within the carton include:

a. "Cardiovascular disease is the #1 health threat in the United States";

b. "40% of deaths in the United States are due to cardiovascular disease";

• "1 in 5 adults has some form of cardiovascular disease";

c. "BAYER Aspirin can help prevent recurrent heart attacks and ischemic strokes";

d. "It has been proven that regular aspirin use can prevent 1 out of 4 heart attacks among patients with a previous event";

e. "BAYER Aspirin can reduce the risk of recurrent ischemic stroke by up to 22%";

f. "BAYER Aspirin can help prevent blood clots from forming, which helps ensure that blood keeps flowing to your heart and your brain"; and

g. "If I am taking BAYER Aspirin to prevent recurrent heart attacks and strokes, can I also take it for occasional relief of pain?"

35. Thus, Bayer intended to and did deceive consumers into believing that Bayer Calcium was approved by the FDA as safe and effective to mitigate, treat, or prevent cardiovascular-related diseases.

3. The FDA sent Bayer a warning letter concerning Bayer Calcium on October 27, 2008

36. On October 27, 2008, the FDA sent a warning letter to Bayer regarding the sale of Bayer Calcium.

37. According to the FDA, as labeled, Bayer Calcium is a "drug" under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(g)(1)(B)), because it is intended to be used as an internal analgesic and to mitigate, treat, or prevent disease (specifically, heart disease and osteoporosis), and under section 201(g)(1)(C) of the Act (21 U.S.C. § 321(g)(1)(C)) because it is intended to affect the structure or function of the body. When a drug and a dietary ingredient are combined into a single dosage form, the combination becomes a "drug" under section 201(g) of the Act, 21 U.S.C. § 321(g).

38. According to the FDA, based on the combination of active drug ingredients (*i.e.*, aspirin and calcium carbonate) and their combined labeled uses in mitigating, treating, or preventing cardiovascular-related diseases and osteoporosis, Bayer Calcium is a new drug within the meaning of section 201(p) of the Act, 21 U.S.C. § 321(p), and 21 C.F.R. § 310.3(h), because it is not generally recognized as safe and effective for its labeled uses.

39. According to the FDA, Bayer Calcium is not subject to the FDA's OTC Drug Review, because no product formulated with these active ingredients and labeled for use by consumers for these intended uses has previously been commercially marketed, and the FDA has never proposed that such a product be included in that Review. Thus, the current marketing of Bayer Calcium violates section 505(a) of the Act (21 U.S.C. § 355(a)) because it is a new drug and it is not the subject of an approved new drug application.

40. The FDA further warned Bayer that Bayer Calcium is misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), because it does not bear adequate directions for its intended uses, *i.e.*, for treating osteoporosis, for preventing heart attacks, and for preventing/ treating heart disease in general.

41. "Adequate directions for use" is defined in 21 C.F.R. § 201.5 as "directions under which the layman can use a drug safely for the purposes for which it is intended." Thus, if an indication requires the supervision of a practitioner licensed to prescribe drugs, adequate directions for use cannot be written for an OTC product for that indication.

42. According to the FDA, the osteoporosis treatment and cardiovascular-related indications require the supervision of a practitioner licensed to prescribe drugs. Indeed, with regard to aspirin, when the Agency finalized the regulations for the professional labeling for aspirin (21 C.F.R. § 343.80, 63 FR 56802, 56809, Oct. 21, 1998), it explicitly rejected a comment recommending that FDA allow consumer-directed OTC labeling for aspirin for various cardiovascular indications, stating:

> The Agency considers the conditions and uses of aspirin that are the subject of this final rule to require the supervision of a physician (or other practitioner licensed to prescribe drugs) to ensure safe use . . . It is not possible, in OTC drug product labeling, to provide adequate directions and warnings to enable the layperson to make a reasonable self assessment of these factors

> [relating to the need for drug therapy and its safety for these purposes].

As described in 21 C.F.R. § 343.80, cardiovascular indications are permissible only in the professional labeling for aspirin. Under that regulation, manufacturers are not permitted to disseminate labeling for their OTC aspirin products to lay consumers for cardiovascular-related indications.

43. Bayer also misleads and deceives consumers regarding the duration for which it can be safely used.

C. Bayer Deceived Consumers Into Buying Bayer Heart Advantage For The Treatment Of Hypercholesterolemia And Coronary Heart Disease Despite Knowing That The FDA Had Not Approved It For Sale

1. Bayer preyed on the public's fears of high cholesterol and heart disease

44. Cholesterol is a soft, fat-like, waxy substance that is normally found in the bloodstream and the body's cells. Cholesterol is used for producing cell membranes and some hormones, and serves other needed bodily functions. But having high levels of blood cholesterol, a condition called hypercholesterolemia, is a major risk for coronary heart disease (which leads to heart attack) and for stroke.

45. As Bayer states on its website:

> According to the American Heart Association, more than 100 million Americans have high cholesterol levels and every 26 seconds an American will suffer a coronary event.

http://www.bayeraspirin.com/cholest_heart.htm (accessed November 3, 2008).

46. Preying on the public's fears of high cholesterol and heart disease, Bayer marketed Bayer Heart Advantage as intended for long-term daily use in preventing heart attacks and lowering cholesterol, and therefore in preventing and treating cardiovascular disease and hypercholesterolemia.

47. For example, Bayer included claims on the product's packaging such as "Plus Cholesterol Lowering Phytosterols" and "Phytosterols, to help lower bad cholesterol" that imply that the product may be used to treat, mitigate, or prevent hypercholesterolemia and coronary heart disease. However, such claims are required to have FDA approval before they can be made or the drug sold to the public.

48. Each caplet (tablet) of Bayer Heart Advantage contains, among other ingredients, 81 mg of aspirin and 400 mg of phytosterols. The product is prominently labeled as containing these ingredients (*e.g.*, "BAYER ASPIRIN" and "ASPIRIN PLUS CHOLESTEROL LOWERING PHYTOSTEROLS"). It is also clearly labeled as an "ANALGESIC/ PHYTOSTEROL SUPPLEMENT." The labeling also prominently describes this product as the "The Only Product That Contains ... • Aspirin, to protect your heart by keeping your blood flowing freely [and] • Phytosterols, to help lower bad cholesterol ....."

49. Regarding the phytosterols in Bayer Heart Advantage, the carton labeling also includes a health claim about phytosterols and reduced risk of heart disease (*see* 21 C.F.R. § 101.83) stating:

> DIETARY SUPPLEMENTS OR FOOD CONTAINING AT LEAST 400MG PER SERVING OF FREE PHYTOSTEROLS, EATEN TWICE A DAY WITH MEALS FOR A DAILY TOTAL INTAKE OF AT LEAST 800 MG, AS PART OF A DIET LOW IN SATURATED FAT AND CHOLESTEROL, MAY REDUCE THE RISK OF HEART DISEASE BY LOWERING BLOOD CHOLESTEROL. EACH BAYER ASPIRIN WITH HEART ADVANTAGE DUO-CAP CONTAINS 400MG OF FREE PHYTOSTEROLS.

50. In fact, on its website, Bayer provides misleading statements designed to confuse consumers that Bayer Heart Advantage – and specifically the phytosterols in combination with aspirin – has received regulatory approval. For example, Bayer states:

> Phytosterols, a natural plant-based ingredient, have been proven to lower cholesterol. Phytosterols reduce a person's LDL cholesterol level by helping block the absorption of cholesterol from the digestive tract. The FDA has recognized the use of phytosterols (at least 800mg a day in divided doses) as part of a low-fat diet to cut the risk of heart disease.

http://www.bayeraspirin.com/cholest_heart.htm (last accessed November 3, 2008).

51. Regarding the use of Bayer Heart Advantage as a source of aspirin, the Drug Facts panel states that the analgesic is intended to treat pain. However, other statements and representations on the package suggest that Bayer Heart Advantage is also intended for long-term daily use in preventing heart attacks and lowering cholesterol, and therefore in preventing and treating cardiovascular disease and hypercholesterolemia.

2. Bayer made misleading and deceptive claims that Bayer Heart Advantage could be used to treat cardiovascular disease without a doctor's supervision despite knowing this conduct was illegal

52. In addition, Bayer Heart Advantage does not bear adequate directions for its intended uses, *i.e.*, for preventing heart attacks and preventing/treating heart disease in general.

53. "Adequate directions for use" is defined in 21 C.F.R. § 201.5 as "directions under which the layman can use a drug safely for the purposes for which it is intended."

54. Thus, if an indication requires the supervision of a practitioner licensed to prescribe drugs, adequate directions for use cannot be written for an OTC product for that indication.

55. With regard to aspirin, when the FDA finalized the regulations for the professional labeling for aspirin (21 C.F.R. § 343.80) (63 FR 56802, 56809) (Oct. 21, 1998), it explicitly rejected a comment recommending that the FDA allow consumer-directed OTC labeling for aspirin for various cardiovascular indications, stating:

> The Agency considers the conditions and uses of aspirin that are the subject of this final rule to require the supervision of a physician (or other practitioner licensed to prescribe drugs) to ensure safe use ... It is not possible, in OTC drug product labeling, to provide adequate directions and warnings to enable the layperson to make a reasonable self assessment of these factors [relating to the need for drug therapy and its safety for these purposes].

As described in 21 C.F.R. § 343.80, cardiovascular indications accordingly are permissible only in the professional labeling for aspirin. Under that regulation, manufacturers are not permitted to disseminate labeling for their OTC aspirin products to lay consumers for cardiovascular-related indications.

56. Despite this knowledge, Bayer directly flouted the regulations and deceived consumers into believing that they could purchase Bayer Heart Advantage to prevent, treat and mitigate cardiovascular-related diseases without the supervision of a physician.

57. In fact, that is the entire purpose of Bayer's consumer healthcare division, which is responsible for the marketing and sale of the Combination Aspirins, *i.e.*, to encourage consumers to treat and prevent diseases through their own choice (as opposed to a physician's choice) of medication. In information provided to investors regarding its consumer care division, Bayer states:

> An increasing number of people worldwide are choosing their own medication for the prevention or treatment of non-severe diseases. Many of them trust tried-and-tested non-prescription or over-the-counter (OTC) medicines offered by the Consumer Care Division of Bayer HealthCare. Take Aspirin for example: The global awareness of this over 100-year old brand is almost unrivaled.

See Bayer HealthCare, Background Information (as of June 2007).

58. Yet despite Bayer's deceptive marketing, neither Combination Aspirin was a "tried-and-tested" drug approved by the FDA for its marketed purposes.

3. The FDA sent Bayer a warning letter concerning Bayer Heart Advantage on October 27, 2008

59. On October 27, 2008, the FDA sent a warning letter to Bayer regarding the sale of Bayer Heart Advantage.

60. According to the FDA, as labeled, Bayer Heart Advantage is a "drug" under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 321(g)(1)(B), because it is intended to be used as an internal analgesic and to mitigate, treat, or prevent disease (specifically, heart disease and hypercholesterolemia), and under section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C), because it is intended to affect the structure or function of the body.

61. According to the FDA, based on the combination of active drug ingredients (*i.e.*, aspirin and phytosterols) and their combined labeled use in mitigating, treating, or preventing cardiovascular-related diseases, as described above, Bayer Heart Advantage is a new drug within the meaning of section 201(p) of the Act, 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h), because it is not generally recognized as safe and effective for its labeled uses.

62. Moreover, the FDA advised Bayer that Bayer Heart Advantage is not subject to OTC Drug Review, because no product formulated with these active ingredients and labeled for these intended uses has previously been commercially marketed, and the Agency has never proposed that such a product be included in that Review. Thus, the current marketing of Bayer Heart Advantage violates section 505(a) of the Act, 21 U.S.C. § 355(a), because it is a new drug and it is not the subject of an approved new drug application.

63. In sum, the FDA concluded that Bayer's labeling of Bayer Heart Advantage "is false or misleading…."

D. Bayer's Condict Injured Plaintiffs And The Class Members

64. Based on Bayer's misleading and deceptive sales scheme, Bayer was able to charge a premium for the illegal Combination Aspirins over the costs of approved OTC aspirins.

65. For example, a bottle of 60 tablets of Bayer Heart Advantage (81 mg aspirin) cost $10.99 at www.drugstore.com (approx. cost of $.18/pill) and $11.99 at www.walgreens.com (approx. cost of $.20/pill), whereas a low-dose aspirin that did not make similar unapproved and deceptive claims could be purchased at www.drugstore.com for $5.49 for a bottle of 500 tablets (approx. $.01/pill)[2] or at www.walgreens.com for $4.99 for two bottles of 120 pills each (approx. $.02/pill).[3]

66. Similarly, Bayer Calcium is priced at a premium to low-dose aspirins that do not make similar unapproved and deceptive claims. At www.drugstore.com and www.walgreens.com,[4] a bottle of 60 tablets of Bayer Calcium (81 mg aspirin) costs $7.49, or at a cost of approximately $.12 per pill compared to one or two cents per pill as reflected above.

67. Plaintiffs and the Class members they seek to represent suffered economic damages by purchasing these unapproved products, and are entitled to a full refund for their purchases.

CLASS ACTION ALLEGATIONS

68. Plaintiffs bring this action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of themselves and a Class defined as follows:

> All persons who paid, in whole or in part, for "BAYER WOMEN'S Low Dose Aspirin + CALCIUM" and / or "BAYER

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[2] *See* http://www.drugstore.com/products/prod.asp?pid=181455&catid=42 (last accessed November 3, 2008).

[3] *See* http://www.walgreens.com/store/product.jsp?CATID=304742&navAction=jump&navCount=1&nug=VPD&skuid=sku3177584&id=prod3178751 (last accessed November 3, 2008).

[4] Both sites were last accessed on November 3, 2008.

ASPIRIN With HEART ADVANTAGE" for personal, family or household uses.

Excluded from the Class are Defendant, any entity in which Defendant has a controlling interest, and Defendant's legal representatives, predecessors, successors, assigns, and employees.

69. The definition of the Class is unambiguous. Plaintiffs are both members of the Class they seek to represent. The Class members can be notified of the class action through publication and direct mailings to address lists maintained in the usual course of business by Defendant and retail pharmacies.

70. The Class members are so numerous that their individual joinder is impracticable. The precise number of Class members is unknown at this time but, based on Defendant's reported sales figures, it is clear that the number greatly exceeds the number to make joinder possible.

71. Common questions of law and fact predominate over the questions affecting only individual Class members. Some of the common legal and factual questions include:

a. Whether Bayer's conduct as set forth herein constitutes the act, use or employment of an unconscionable commercial practice, deceptive, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in violation of the New Jersey Consumer Fraud Act;

b. Whether New Jersey law applies to the proposed nationwide Class;

c. Whether Defendant violated consumer protection statutes and/or false advertising statutes and/or state deceptive business practices statutes;

d. Whether Defendant violated the common law of unjust enrichment; and

e. The nature and extent of damages and other remedies to which the conduct of Defendant entitles the Class members.

72. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by the Class members. Similar or identical statutory and common law violations and deceptive business practices are involved. Individual questions, if any, pale by comparison to the numerous common questions that predominate.

73. The injuries sustained by Plaintiffs and the Class members flow, in each instance, from a common nucleus of operative facts – Defendant's misconduct. In each case Defendant marketed and sold Bayer Calcium and Bayer Heart Advantage by misleading and deceiving Plaintiffs and the Class members that the Combination Aspirins could be legally sold, had been approved by the FDA, and had been proven to be safe and effective for their marketed purposes.

74. Plaintiffs and the Class members have been damaged by Defendant's misconduct. Plaintiffs and the Class members have paid a premium price for Bayer Calcium and Bayer Heart Advantage, products which would not have been legally sold or purchased in the absence of Defendant's marketing campaigns and deceptive scheme.

75. Plaintiffs' claims are typical of the claims belonging to absent Class members. Mr. and Mrs. Blank both paid for and ingested Bayer Heart Advantage capsules that Defendant manufactured, marketed, and sold without FDA approval, and that were represented to contain

both an 81mg dose of aspirin (for prophylaxis) and a sufficient amount of phytosterols to provide a cholesterol-lowering effect. Further, Mrs. Blank paid for and ingested Bayer Calcium capsules that Defendant manufactured, marketed, and sold without FDA approval, and that were represented to contain both an 81mg dose of aspirin (for prophylaxis) and a sufficient amount of calcium to prevent osteoporosis.

76. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs are familiar with the basic facts that form the bases of the Class members' claims. Plaintiffs' interests do not conflict with the interests of the other Class members that they seek to represent. Plaintiffs have retained counsel competent and experienced in Class action litigation and intend to prosecute this action vigorously. Plaintiffs' counsel have successfully prosecuted many complex Class actions, including consumer protection Class actions. Plaintiffs and their counsel will fairly and adequately protect the interests of the Class members.

77. The class action device is superior to other available means for the fair and efficient adjudication of the claims belonging to Plaintiffs and the Class members. The relief sought for each individual Class member is small given the burden and expense of individual prosecution of the potentially extensive litigation necessitated by the conduct of Defendant. Furthermore, it would be virtually impossible for the Class members to seek redress on an individual basis. Even if the Class members themselves could afford such individual litigation, the court system could not.

78. Individual litigation of the legal and factual issues raised by the conduct of Defendant would increase delay and expense to all parties and to the court system. The class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale and comprehensive supervision by a single court.

Given the similar nature of the Class members' claims and the absence of material differences in the state statutes and common laws upon which the Class members' claims are based, a nationwide Class will be easily managed by the Court and the parties.

CAUSES OF ACTION

COUNT I
Violation of the New Jersey Consumer Fraud Act

79. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

80. At all relevant times, the New Jersey Consumer Fraud Act ("CFA") has prohibited consumer fraud in connection with the sale or advertisement of merchandise:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.

See C.F.A. § 56:8-2.

81. Pursuant to the CFA, Defendant had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of the Combination Aspirins to Plaintiffs and the Class members.

82. Defendant intended that Plaintiffs and the Class members rely on its materially deceptive practices and purchase the Combination Aspirins as a consequence of the deceptive

practices, including Defendant's misrepresentations and omissions of material fact with respect to the true nature of the Combination Aspirins:

a. Defendant's promotions of Bayer Calcium and Bayer Heart Advantage as safe approved and effective drugs for the treatment of osteoporosis and coronary heart disease, respectively, were deceptive, unfair, and unlawful in that neither had been approved for sale for their marketed purposes and both were promoted solely for financial reasons;

b. Defendant's conduct was unfair, unlawful and deceptive in that Defendant knew neither Combination Aspirin had been approved for sale for the public but omitted to disclose these facts to Plaintiffs and the Class members;

c. Defendant omitted material information known to it in order to induce Plaintiffs and the Class members to purchase the Combination Aspirins; and

d. Defendant committed unlawful acts by promoting, advertising and selling the Combination Aspirins in a manner that violated the Federal Food, Drug and Cosmetic Act.

83. Defendant's deceptive representations and material omissions to Plaintiffs and the Class members constitute unfair and deceptive acts and practices under the CFA.

84. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiffs and the Class members.

85. Plaintiffs and the Class members were actually deceived by Defendant's misrepresentations.

86. As a proximate result of Defendant's misrepresentations, Plaintiffs and the Class members have suffered ascertainable losses, in an amount to be determined at trial.

COUNT II

BREACH OF EXPRESS WARRANTIES

87. Plaintiffs restate and incorporate herein by reference the preceding paragraphs as if fully set forth herein.

88. Defendant is in the business of selling OTC products to consumers such as Plaintiffs and the members of the Class, including but not limited to OTC aspirin products of the kind sold to Plaintiffs and the members of the Class.

89. Plaintiffs and the members of the Class purchased Defendant's Combination Aspirin products.

90. Defendant expressly warranted that Bayer Heart Advantage and Bayer Calcium were safe and effective.

91. The Combination Aspirins do not conform to these express representations because they have not been approved by the FDA as safe and effective medications. Thus, Defendant breached its express warranties.

92. As a direct and proximate result of the breach of said warranties, Plaintiffs and the Class members suffered and/or will continue to be harmed and suffer economic loss.

93. Plaintiffs and the Class members did rely on the express warranties of the Defendant herein.

94. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Combination Aspirins had not been approved by the FDA for any purpose other than pain relief.

95. Bayer's conduct breached its express warranties in violation of, among other state express warranty laws, N.J. Stat. Ann. § 12A:2-313.

96. The above statute does not require privity of contract to recover for breach of express warranty.

97. Within a reasonable time after they knew or should have known of such breach, Plaintiffs, on behalf of themselves and members of the Class, placed Bayer on notice thereof.

98. As a direct and proximate result of the foregoing acts and/or omissions, Plaintiffs and the Class members have suffered damages entitling them to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

COUNT III
BREACH OF IMPLIED WARRANTIES

99. Plaintiffs restate and incorporate herein by reference the preceding paragraphs as if fully set forth herein.

100. Defendant is in the business of selling OTC products to consumers such as Plaintiffs and the members of the Class, including but not limited to OTC aspirin products of the kind sold to Plaintiffs and the members of the Class.

101. Plaintiffs and the members of the Class purchased Defendant's Combination Aspirin products.

102. At all times herein mentioned, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed Bayer Heart Advantage and Bayer Calcium.

103. At the time Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Combination Aspirins for use by Plaintiffs and the Class members, Defendant knew of the use for which the Combination Aspirins were intended, and impliedly warranted the products to be of merchantable quality.

104. Defendant's representations and warranties were false, misleading, and inaccurate, in that the Combination Aspirins were not of merchantable quality because they had not been approved by the FDA.

105. Plaintiffs and the Class members did rely on said implied warranty of merchantability.

106. Plaintiffs and the Class members reasonably relied upon the skill and judgment of Defendant as to whether the Combination Aspirins had been approved by the FDA and were of merchantable quality.

107. The Combination Aspirins were injected into the stream of commerce by Defendant despite the fact that they had not been approved by the FDA and were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

108. Defendant breached the aforesaid implied warranties, as the Combination Aspirins were not fit for their intended purposes and uses as they had not been approved by the FDA.

109. As a direct and proximate result of the breach of said warranties, Plaintiffs and the Class members suffered and/or will continue to be harmed and suffer economic loss.

110. Bayer's conduct breached its implied warranties regarding its products under state implied warranty laws including N.J. Stat. Ann. § 12A:2-314 and § 12A:2-315.

111. This state does not require privity of contract to recover for breach of implied warranty.

112. Within a reasonable time after they knew or should have known of such breach, Plaintiffs, on behalf of themselves and members of the Class, placed Bayer on notice thereof.

113. As a direct and proximate result of the foregoing acts and/or omissions, Plaintiffs and the Class members have suffered damages, and are entitled to compensatory damages, punitive damages, costs and reasonable attorneys' fees.

COUNT IV
UNJUST ENRICHMENT

114. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

115. At all relevant times, Defendant designed, manufactured, produced, marketed and/or sold the Combination Aspirins.

116. Defendant has benefitted from its unlawful acts by receiving payments for the sales of the products which were illegally on the market. Defendant knew that the Combination Aspirin products did not have FDA approval, and knew that it did not have the authority to sell the products as constituted.

117. Plaintiffs and the Class members, without knowing that the Combination Aspirins did not have regulatory approval and were not approved for sale, conferred non-gratuitous benefits upon Defendant by paying for the Combination Aspirins.

118. Defendant appreciated, or had knowledge of the non-gratuitous benefits conferred upon it by Plaintiffs and the Class members.

119. Defendant accepted or retained the non-gratuitous benefits conferred by Plaintiffs and the Class members, with full knowledge that, as a result of Defendant's unconscionable

wrongdoing, Plaintiffs and the Class members were not receiving products of the high quality, nature, fitness, or value as reasonable consumers expected. Allowing Defendant to retain the non-gratuitous benefits Plaintiffs and the Class members conferred would be unjust and inequitable under these circumstances.

120. Because Defendant's retention of the non-gratuitous benefits conferred by Plaintiffs and the Class members would be unjust and inequitable, Plaintiffs and the Class members are entitled to, and hereby seek disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits in a manner established by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class members request that the Court enter an order or judgment against Defendant including the following:

a. Certification of the action as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; appointment of Plaintiffs as the Class Representatives and appointment of their counsel as Class Counsel;

b. Damages in the amount of monies paid for the Combination Aspirins;

c. Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;

d. Pre-judgment and post-judgment interest on such monetary relief;

e. Other appropriate injunctive relief;

f. The costs of bringing this suit, including reasonable attorneys' fees; and

g. All other relief to which Plaintiffs and the Class members may be entitled at law or in equity.

JURY DEMAND

Plaintiffs hereby demand trial by jury on their own behalf, and on behalf of the absent Class members, on all issues and claims presented above.

Dated: February 11, 2011

Respectfully Submitted,

By:/s/ **Elizabeth A. Fegan**

Elizabeth A. Fegan
Daniel J. Kurowski
Hagens Berman Sobol Shapiro LLP
1144 W. Lake Street, Suite 400
Oak Park, IL 60301
Ph: (708) 628-4960
Fax: (708) 628-4950
Email: beth@hbsslaw.com
dank@hbsslaw.com

David J. Cohen, Esq.
Kolman Ely, P.C.
414 Hulmeville Avenue
Penndel, PA 19147
Ph: (215) 750-3134
Email: dcohen@kolmanlaw.net

Counsel for Plaintiffs